

**Maryland Board of Pharmacy
Public Meeting
Minutes**

Date: October 20, 2010

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner	X		3	1
Chason, D.	Commissioner	X		3	1
Finke, H.	Commissioner	X		4	0
Gavvani, M. Z.	Commissioner	X		2	0
Handelman, M.	Commissioner	X		4	0
Israbian-Jamgochian, L.	Commissioner/Treasurer	X		4	0
Matens, R.	Commissioner	X		4	0
Souranis, M.	Commissioner//President	X		4	0
St. Cyr, II, Z. W.	Commissioner	X		3	1
Taylor, D.	Commissioner	X		4	0
Taylor, R.	Commissioner/Secretary	X		3	1
Zimmer, R.	Commissioner	X		3	1
Bethman, L.	Board Counsel	X		4	0
Gibbs, F.	Board Counsel	X		4	0
Banks, T.	MIS Manager	X		4	0
Gaither, P.	Administration and Public Support Manager	X		4	0
Jeffers, A.	Legislation/Regulations Manager	X		3	1
Naesea, L.	Executive Director	X		4	0
Waddell, L.	Executive Secretary	X		4	0

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
I. Executive Committee Report(s)	A. M. Souranis, Board President	<p><i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i></p> <ol style="list-style-type: none"> M. Souranis called the Public Meeting to order at 9:27 a.m. M. Souranis requested all meeting attendees to introduce themselves and to remember to sign the guest list before leaving the meeting. M. Souranis asked guest to (Please indicate on sign-in sheet if you are requesting CE Units for attendance). M. Souranis reported that guest will be given packets of materials so that they can follow meeting discussions. He requested that all guest return their draft packets before they leave the meeting M. Souranis asked all members of the Board with a conflict of interest relating to any item on the agenda to notify the Board at this time or when the issue is addressed in the agenda. Review & Approval of Minutes of September 15,, 2010 <ol style="list-style-type: none"> Page 2 Section 2b change to "League for disability". Page 5, Section C, change to "Janet Seeds Board of Pharmacy". Page 7, Section E. change to "Grandfathered status". Page 8, Section C, change to "engage and Board and PEAC". Page 16, Section III, Item 3a add " M. Handelman seconded the motion". 	5. Motion: D. Taylor made a motion to approve the September minutes as amended.	5. Board Action: The Board voted to approve the minutes.

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		<p>f. Page 24, Section IV, Item B, change to “change labeling on single dose packaging”.</p> <p>6. M. Souranis appointed D. Chason and H. Finke as liaisons for PEAC committee.</p>	R. Zimmer seconded the motion.	
II. Staff Operations Report (s)	A. L. Naesea, Executive Director	<p>1. L. Naesea reported on the following Operations Updates</p> <p>The Board currently has 6 vacancies. The Board has received approval to recruit for three (3) positions and the other 3 positions are awaiting State freeze exemptions. Keisha Wise is on maternity leave and the Board is awaiting a temp to fill her position.</p> <p>2. Meeting Updates</p> <p>a. The Board met with stakeholders regarding physician dispensing on 09/30/2010. The Board of Physicians, Division of Drug Control, and the Laboratory Administration.</p> <p>b. A Drug Therapy Management meeting scheduled for October 13, 2010 was canceled by the Board of Physicians which sent a letter of concerns regarding the Joint Committee review process. A draft response be prepared for Board review.</p>		
	B. P. Gaither, APS Manager	<p>1. P. Gaither reported the following:</p> <p>a. The Board is awaiting the receipt of resumes for the Pharmacy Inspector position.</p> <p>b. Three pharmacists have submitted applied for the Pharmacist Compliance Officer position. P. Gaither reported that - those candidates were screen by the DHMH Department of Human Resources and interviews are being scheduled.</p> <p>c. Tthe contract for help desk staffing has been extended for another 6 months.</p> <p>2. The. Gantack will be working g with Systems Automation on the project. The contract was sent to the contract office. We will begin contracting before our next meeting.</p> <p>3. The contract for the newsletter needs to be re-worked.</p> <p>4. Public Relations Committee Report:</p>		

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		<p>a. J. Seeds is working with T. Banks on email addresses for pharmacists. Email addresses will be requested on all forms. L. Bradley-Baker will make comments on the Board's Continuing Education (CE) Breakfast</p> <p>b. L. Bradley-Baker reported that the CE Breakfast was held on October 3, 2010 at the Radisson at Cross Keys. The event entailed two and one half hours on topics related to Medical Marijuana, the Prescription Drug Repository Program, the P3 Program, Pharmacist consulting, and Drug Therapy Management. Staff and Board members present included, L. Naesea, P. Gaither, J. Seeds, A. Page, N. Dupye, D. James, M. Souranis, A. Jeffers, L. Bradley-Baker, R. Zimmer, H. Finke, R. Taylor, D. Taylor, R. Mates, L. Bradley-Baker publicly thanked Janet Seeds for a job well done.</p> <p>4. Emergency Preparedness Task Force Update-Report by D. Taylor Approval of DHMH Emergency Protocol and Board Letter</p> <p>D. Taylor announced that after 6 ½ years of effort, the protocols were finally approved by DHMH. If there would be an emergency event, the protocols deal exclusively with pharmacists allowable actions. The protocols allow the Governor to pick from the listed actions, those that would become a part of an executive order. It could allow pharmacist to dispense without a prescription, make therapeutic substitutions, omit some labeling requirements, operate a pharmacy where the Board approves, and bring pharmacists, and technicians from out of state as long as they are certified and licensed. The protocol was reviewed by Fran Phillips, Deputy Secretary and Secretary Colmers. D. Taylor thanks the Board for supporting the long process.</p> <p>Don Taylor will ask Fran Phillips if the protocol may be posted on the website. L. Naesea acknowledged and thanked Don Taylor, Task Force Members and current and past Board members for their hard work.</p>		
	C. T. Banks, MIS Manager	<p>T. Banks reported on the following Unit Updates</p> <p>a. The Board will assign a team of Board members and staff to consider all the new automation project factors and help avoid pitfalls. Team members will include R. Matens, M. Gavvani, R. Taylor, Z. St. Cyr L. Naesea, T. Banks and M. Hsu. T. Banks will send out the statement of work to the team and asked that the team begin to brainstorm ideas for addressing the various project phases.</p>		
	D. L. Naesea,	1. PEAC Update - T. Tomassello reported on PEAC's recent CE		

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	Acting Compliance Manager	program and the “Two Paths of Resolution” flowchart for clients that enroll in PEAC’s program. PEAC is available to reach out to pharmacists and technicians to help with rehabilitation before they enter the Board formal disciplinary process.		
	E. A. Jeffers, Rgs/Lgs. Manager	<p>1. Status of Proposed Regulations – A. Jeffers reported on the status of the following regulations and future regulations.</p> <p><u>a. 10.34.03 Inpatient Institutional Pharmacy</u></p> <p>Submitted for publication on October 4, 2010.</p> <p><u>b. 10.34.20 Format of Prescription Transmission</u></p> <p>Effective October 4, 2010</p> <p><u>c. 10.34.25 Delivery of Prescriptions</u></p> <p>Submitted for publication on August 4, 2010.</p> <p><u>d. 10.34.28 Automated Medication Systems</u></p> <p>Re-proposal submitted for publication on September 24, 2010.</p> <p><u>e. 10.34.35 Home Infusion Pharmacy Services</u></p> <p>Proposal to be released for informal comment.</p> <p><u>d. 10.13.01 Dispensing of Prescription Drugs by a Licensee</u></p> <p>A meeting was held with representatives from the stakeholder Boards per direction from Wendy Kronmiller on September 30, 2010. Wendy will schedule another meeting in the future.</p> <p>A. Jeffers summarized the meeting and R. Taylor and H. Finke described how the Board of Physicians, Division of Drug Control and the Laboratory Administration walked out of the meeting. Some consensus was reached regarding inspections with the Board of Podiatric Medical Examiners and the Board of Dental Examiners. They are amenable to inspections, so long as it would not hinder practitioners obtaining an initial dispensing permit.</p>		

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		<p>2. Status of Proposed Legislation</p> <p>a. Legislative Proposal submitted to the Office of Governmental Affairs on July 14, 2010: Health Occupations - Pharmacy – Licensure of Pharmacists</p> <p>b. Legislative Proposal completed - to the Office of Governmental Affairs on August 20, 2010: Health-General – Prescription Drug Repository Program – Disposal</p> <p>c. Meeting with Senator Carter Conway scheduled for December.</p> <p>d. Met with Chairman Hammen on October 15, 2010. Anna Jeffers reported that Mike Sourains, Rodney Taylor and she met with Chairman Hammen, Linda Stahr and Patrick Dooley to discuss possible sponsors for legislation: 1) to license any pharmacist practicing pharmacy in Maryland including those working at non-resident pharmacies, PBMs and insurance companies; and 2) to expand the purpose of the Prescription Drug Repository Program to include disposal. Chairman Hammen would like additional information on other states that require licensure of out of state pharmacists and also information on PBMs. Chairman Hammen liked the expansion of the Prescription Drug Repository Program and will look for a sponsor for us.</p>		
III. Committee Reports	A. R. Zimmer, Chair, Practice Committee	<p>1. Review of Draft Regulations</p> <p>a. <u>10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities</u> 10.34.23v4_9794_1 Reproposal 100410</p> <p>Board approval was sought for adding clarification for labeling of blister cards to the re-proposal. The re-proposal will be submitted as soon as possible.</p> <p>b. CLIA – Approve Letter with Board Comments.</p> <p><u>Draft email to Michael Wajda concerning teaching pharm & Lab fees</u></p>	<p>1a. Motion was made to approve the re-proposal as presented:</p> <p>seconded: Don</p> <p>1b. Motion: seconded: Tabled back to Practice to draft</p>	<p>1. a. Board Action: The Board voted to approve the motion.</p> <p>1b. Board Action: The Board voted to approve the motion.</p>

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		<p>Thank you for the Labs Administration's September 27, 2010 response to the concerns of the Board of Pharmacy. The Board applauds your efforts to craft regulations that address pharmacists performing CLIA waived tests in Maryland.</p> <p>The Board has some additional concerns that the Board hopes you would address. In your response to the Board's 4th concern you mentioned that training and counseling patients for self-testing on the patient's own instrument is not considered the operation of a laboratory. In the community pharmacy, the patient often asks the pharmacist to perform the test for the patient so that the patient can learn how to perform the test themselves. When a pharmacist is teaching or assisting an individual patient to use a testing device (e.g., glucometer, etc.) for self-testing and the pharmacist is performing the test for the patient, please confirm that since this is <u>not</u> considered to be a "laboratory" a State laboratory license or CLIA certificate is not required.</p> <p>Additionally, please confirm that the Labs Administration will not require community pharmacists, who only perform waived CLIA tests in order to teach patients how to perform self testing, to apply for and pay a fee for a CLIA waiver certificate. The legislation that was withdrawn during the last session did not include the imposition of fees.</p> <p>2. Draft Response Letters</p> <p>a. Mary Caldwell, City Pharmacy of Elkton</p> <p><u>Ownership of the physical hard-copy rx in assisted living</u></p> <p><u>Transfers - Assisted Living facilities & ownership of rx 072710</u></p> <p><u>Email Re ownership of the physical hard-copy prescription assisted living 092210</u></p> <p>The Board of Pharmacy would like to provide additional follow-up information to the response sent to you on July 27, 2010.</p> <p>When an assisted living facility, or long term care facility, decide to change pharmacy vendors there is a standard of practice that is usually followed so that the transition is safe and runs smoothly for the residents of the facility. Once the decision is made to switch to another pharmacy the facility sends a notice to its residents that the facility will be changing pharmacy vendors. Residents may choose to use the pharmacy vendor selected by the assisted living facility or any pharmacy of their choice.</p>	<p>an article to send to Michael Wajda for clarification.</p> <p>2a. Motion: Moved to accept the letter with one revision. Add the word "information" in the first sentence.</p> <p>Seconded; D. Chason</p>	<p>2a. Board Action: The Board voted to approve the motion.</p>

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		<p>Before the switch to the new pharmacy vendor, the new pharmacy vendor sends in a team of employees to make copies of the residents' orders so that they may be verified with each resident's physician. The orders are used to dispense medications when the changeover is complete. After the team obtains copies of the existing orders, any new orders are sent to both the old and new pharmacies so that the new pharmacy will have the most current prescribing information on each resident for the date of the changeover.</p> <p>On the date of the change over, the new pharmacy team goes to the facility and goes through the medication cart to make sure that all the appropriate ordered medications are on hand. The new pharmacy supplies any medications that are missing.</p> <p>This transition process is routinely performed so that there is an orderly change over from one pharmacy to another.</p> <p>b. George Garmer, Halethorpe Pharmacy</p> <p>Request for clarification of COMAR 10.34.05</p> <p>Email - Request for clarification of COMAR 10.34.05</p> <p>Thank you for contacting the Maryland Board of Pharmacy concerning COMAR 10.34.05.02C(2)(d) which states "A pharmacy shall be equipped with an inventory management and control system that protects against, detects and documents any instances of theft, diversion or counterfeiting." You asked if this means that you would have to start perpetual inventories for the controls at each of my stores.</p> <p>Please be advised that a perpetual inventory is not required, so long as your software tracks the drugs into, out of, and within the pharmacy so the pharmacist can identify the location of inventory at any time.</p> <p>c. Wan-Chih Tom, Pharmacist's Letter/Prescriber's Letter</p> <p>State Regulations on Generic Substitution Update (MD)</p> <p>Email - State Regs - Generic Substitution Update (MD)</p> <p>Dear Wan-Chih Tom:</p> <p>Thank you for contacting the Maryland Board of Pharmacy requesting an</p>	<p>2b. Motion: Moved to accept the letter Seconded: M. Handelman</p>	<p>2b. Board Action: The Board voted to approve the motion.</p>

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		<p>update of generic substitution information specific to Maryland for the <i>Pharmacist's Letter/Prescriber's Letter's</i> chart of "State Regulations on Generic Substitution". Below you will find responses to your inquiries:</p> <p>1) Does your state require substitution with an AB-rated generic (Orange Book)?</p> <p>Yes.</p> <p>2) If not, what are the requirements for generic substitution in your state?</p> <p>N/A</p> <p>3) If a doctor writes generically for a drug with multiple brand names, is there anything in your state law that would prohibit a pharmacist from selecting the generic version that is to be dispensed?</p> <p>No, so long as the generic medication is AB rated.</p> <p>3. Letters for Board Approval</p> <p>a. Robin Abrams and Ann Rule, Purdue Pharma</p> <p><u>Letter</u></p> <p><u>Protocol</u></p> <p><u>Bottle Tracker Agreement Final- Signed by FDA</u></p> <p><u>Letter from Md Bd of Pharm to Purdue Pharma</u></p> <p>b. All Carter, Walgreens</p> <p><u>Records - electronic - stickerless 082610</u></p> <p><u>Records - electronic - stickerless 083110</u></p> <p><u>Letter Records - electronic - stickerless 092210</u></p> <p>Thank you for contacting the Maryland Board of Pharmacy to address the Board's concerns regarding implementation of Walgreens stickerless program. You described Walgreen's current process for "non-scannable" prescriptions where the prescription is presented to the pharmacist, who first verifies that it is a valid prescription. The pharmacist is then responsible for the</p>	<p>2c. Motion: Moved to accept the letter Seconded: H. Finke</p>	<p>2c. Board Action: The Board voted to approve the motion.</p>

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	B.D. Chason, Chair, Licensing Committee	<p>1. D. Chason recommended the following Technician Training Programs:</p> <p style="padding-left: 40px;">a. Howard County Community College-Program only</p> <p style="padding-left: 40px;">b. Tesst College-was recommended to the Board that pharm techs had taken the program and test but Tesst College was only originally approved for the program only. The Board has drafted a letter to Tesst asking that they resubmit their exam before it can be approved.</p> <p style="padding-left: 40px;">C.Tesst believes that there are 60 graduates that did not take the test. The Board will send a notification to the graduates that they have 90 days to take the test or their license will be revoked.</p> <p style="padding-left: 40px;">d. Forrest Training Program</p> <p>2. Draft Repository Inspection Form</p> <p>3. <u>State Licensing Servicing Letter to MD BOP 12oct10</u></p> <p>4. D. Chason recommended the following Pharmacist Applicants:</p>	<p>1a. Motion: Licensing Committee Seconded: R. Taylor</p> <p>1b. Motion: Licensing Committee Seconded: D. Taylor</p> <p>1c. Motion: Licensing Committee Seconded: D. Chason</p> <p>1d. Motion: R. Matens Seconded: D. Chason</p> <p>2. Tabled back to Licensing Committee</p> <p>3. Tabled back to Licensing Committee</p> <p>4. a Motion: Licensing</p>	<p>1a. Board Action: The Board voted to approve the motion.</p> <p>1b. Board Action: The Board voted to approve the motion.</p> <p>1c. Board Action: The Board voted to approve the motion.</p> <p>1d. Board Action: The Board voted to approve the motion.</p> <p>2. Board Action: The Board voted to approve the motion.</p> <p>3. Board Action: The Board voted to approve the motion.</p> <p>4a. Board Action:</p>

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		<p>a. Melvin Friedman- Pharmacist requesting waiver of (2) Live CE's. Licensing Committee recommends requiring applicant to obtain Live Web CE's and explain that as long as the CEs are listed as 'live' (web or otherwise) they are acceptable. Not waive the requirements</p> <p>b. Aslam Moosa- Pharmacist requesting waiver of reinstatement fee. Licensing Committee recommends denial of request.</p> <p>c. Shahrzad Movafagh- Pharmacist requesting waiver of reinstatement fee. Licensing Committee recommends denial of request.</p> <p>d. Tahani Wanis- Applicant requesting waiver of partial FPGE's requirement (Toefl). Licensing Committee recommends denial of request and that the Board recommend that applicant to re-apply and meet all requirements.</p> <p>5. Licensing Committee recommends that the Board withdraw Berlitzs and used NABP pre screening oral competency exam until the Board finds another company. NABP does not offer a pre screening test.</p>	<p>Committee Seconded R. Zimmer</p> <p>4b. Motion: Licensing Committee Seconded: R. Zimmer</p> <p>4c. Motion: Licensing Committee Seconded: D. Chason</p> <p>4d. Motion: Licensing Committee Seconded: H. Finke</p> <p>5a. Motion: Licensing Committee made a motion to no longer use Berlitz for English proficiency Seconded: R. Matens</p> <p>5b. Tabled back to Licensing Committee for further discussion.</p>	<p>The Board voted to approve the motion.</p> <p>4b. Board Action: The Board voted to approve the motion.</p> <p>4c Board Action: The Board voted to approve the motion.</p> <p>4d Board Action: The Board voted to approve the motion.</p> <p>5b. Board Action: The Board voted to approve the motion.</p>
	C. Bradley-Baker, Chair, Public	<p>Committee Updates</p> <p>The Maryland Pharmacy Coalition voted to support the incorporation of clinic and long term care settings as part of the DTM allowable protocols.</p>		

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	Relations Committee	They have been collecting evidence to go to the legislature regarding their efforts to get more DTM protocols approved.		
	D. L. Israbian-Jamgochian, Chair Disciplinary Committee	Committee Updates: L. Israbian-Jamgochian attended the NABP District I & II meeting in Cooperstown, NY. Where they discussed the proposed agenda for the National meeting in 2011.		
IV. Other Business	A. M. Souranis	None		
	B. Board Member Updates	M. Handelman reported that the Office of Health Care Quality have provided a list of medications that can be purchased in bulk for Long Term Care Facilities only, not Assisted Living. Under certain conditions, a nurse in the long term care facility can act as an agent.		
	B. FYI	1. October CE Programs at University of Maryland School of Pharmacy 2. DEA Issues Policy Statement on Role of Agents in Communicating CS 3. New Board Member Orientation on Monday, November 8, 2010. Z. St. Cyr has volunteered to present the Consumers Board members' perspective at the orientation.		
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at <u>11:53</u> A.M. B. At <u>12:45</u> P.M. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at <u>1</u> P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	Motion: R. Matens made a motion to close the Public Meeting and open a Closed Public Meeting. H. Finke seconded the motion.	Board Action: The Board voted to approve the motion.